

MARKED-UP COPY OF AMENDMENTS TO THE SPECIFICATION

The paragraph beginning on page 1, line 14, and ending on page 1, line 19, is amended herein as follows:

One of the known procedures for treating an enlarged prostate is thermal prostate ~~prostatic~~ therapy. During thermal prostate ~~prostatic~~ therapy, the prostate is heated above body temperature to remove the diseased tissue, whereby returning the prostate to normal size. Immediately after treatment, however, the prostate is still swollen or enlarged due to the therapeutic trauma induced by the procedure. It may take several weeks before the treated prostate recovers and no longer inhibits bladder drainage.

The paragraph beginning on page 8, line 7, and ending on page 8, line 24, is amended herein as follows:

After a medical procedure to treat an obstructed prostate, such as thermal prostate therapy, a patient may experience prostate bleeding while the recently-treated prostate recovers. Another consequence of such medical procedures is bladder outlet obstruction which results from the still-slightly enlarged and recovering prostate. After the procedure, the medical professional (e.g., a physician) that performed the procedure or some other medical professional will monitor the amount of urine and prostate bleeding, and attempt to provide the patient with an open urinary passageway. In order to monitor continuously the bodily fluids from the patient's bladder and prostate, the medical professional(s) attending to the patient need(s) to prevent the patient's external sphincter from closing to allow constant and uninterrupted drainage of those bodily fluids. In general, the attending professional(s) only need(s) to monitor the flow of blood and urine from the patient's urinary system for a few hours. It may, however, take several weeks for the patient's prostate to recover. One of the objects of the

present invention is to provide devices, systems, and methods which will maintain an open passageway throughout the patient's entire urinary system such that constant drainage can be realized for some period of time just after treatment of the prostate, and which also can thereafter provide an open urinary passageway from the bladder through the prostatic section of the urethra while simultaneously allowing normal operation of the patient's external sphincter such that the patient has full and normal control over bladder voiding.

The paragraph beginning on page 11, line 3, and ending on page 11, line 27, is amended herein as follows:

The embodiment of the prostatic stent-catheter system **1** of FIGS. 1 and 2 further comprises a pushing device **12** and a handle **20**. The pushing device **12** has a proximal end **36** and a distal end **34**. The width of the pushing device **12** is sized to fit within the lumens of the prostatic stent **3** and the connecting segment **6**; while the length of the pushing device **12** is sized so that the proximal end **36** can contact the proximal tip **2** of the prostatic stent **3** while the distal end **34** extends beyond the distal end **30** of the releasably connected connecting segment **6**. Therefore, the physician performing the procedure can use the pushing device **12** to contact the proximal tip **2** of the prostatic stent **3** once the prostatic stent-catheter system **1** is already inserted into the patient's body. The pushing device **12** can be made from any material that is flexible enough to conform to the patient's anatomy, but also rigid enough to extend the proximal tip **2** away from the body member **5**. Materials such as stainless steel or polycarbonate meet these criteria. The pushing device **12** can be either straight as shown in FIG. 7 or curved as shown in FIG. 8, to aid in the insertion and placement of the prostatic stent **3** within the prostatic section of the urethra. Extending through the entire pushing device **12** is a lumen capable of receiving a guide wire. At the proximal end **36** of the pushing device **12** is a flange **32** used to connect the proximal tip **2**

to the pushing device 12. The flange 32 also prevents premature separation of the pushing device 12 from the proximal tip 2. The flange 32 is best illustrated in FIG. 9. The other end of the pushing device 12, the distal end 34, is attached to a mechanism 24 located within the handle 20. The mechanism 24 is slidably movable in the proximal and distal directions. Because the mechanism 24 is attached to the pushing device 12, the position of the mechanism 24 determines the position of the pushing device 12 within the prostatic stent-catheter system 1. The handle 20 is attached to the distal end 30 of the connecting segment 6 and remains outside of the patient's body. Therefore, a physician has access to the position of the pushing device 12 at all times during a procedure. Besides the mechanism 24, the handle 20 also includes at least one opening 22 for drainage of fluids from the prostatic stent-catheter system 1.

The paragraph beginning on page 16, line 5, and ending on page 16, line 22, is amended herein as follows:

The prostatic stent-catheter system 1 remains inside the male urinary system 70 until a decrease in prostate bleeding is observed and a physician decides that it is no longer necessary to monitor a patient's bodily fluid excretions. Even though a patient's bodily fluid excretions no longer require monitoring, the patient's prostate 53 may still be obstructed. To prevent bladder outlet obstruction and to promote prostate 53 recovery, a physician may decide to leave the prostatic stent 3 in position, and to remove only the connecting segment 6 portion of the prostatic stent-catheter system 1. To remove the connecting segment 6, the physician first decouples the prostatic stent 3 and connecting segment 6 by pulling on the connecting segment 6 (FIG. 24). The physician is then able to withdraw the connecting segment 6 from the urethra 58 (FIG. 25). Once the connecting segment 6 portion of the prostatic stent-catheter system 1 is removed, the patient's external sphincter opening 56 contracts, allowing the

external sphincter 54 to operate normally and thus allowing the patient to control all bladder functions even though the prostatic stent **3** remains in place. The suture **42** attached to the prostatic stent **3** extends from the distal terminating end **4** through the urethra **58** and terminates just outside the meatus **60**. The suture **42** is thin enough to pass through the contracted external sphincter opening **56** without negatively impacting the operation of the external sphincter or therefore the patient's bladder control. The removal of a prostatic stent **3** may be performed separately at some later time, by either pulling on the suture **42** or through endoscopic means.

MARKED-UP COPY OF AMENDMENTS TO CLAIMS

Claims 1-9 and 13-16 were amended as follows:

1. (Amended) A prostatic stent, comprising:
 - (a) a body member including a distal terminating end, a proximal end portion, and a lumen extending within the body member, the body member sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of the~~an~~ external sphincter; and
 - (b) a retaining member extending from the proximal end portion of the body member, the retaining member being collapsible and expandable.
2. (Amended) The prostatic stent~~device~~ of claim 1 wherein a proximal portion of the retaining member is tapered.
3. (Amended) The prostatic stent~~device~~ of claim 1 wherein the retaining member is formed integrally with the body member.
4. (Amended) The prostatic stent~~device~~ of claim 1 wherein the retaining member is biased in an expanded state.
5. (Amended) The prostatic stent~~device~~ of claim 1 wherein the retaining member comprises at least two arms biased in the expanded state.
6. (Amended) The prostatic stent~~device~~ of claim 1 wherein the body member comprises at least one side opening in communication with the lumen.

7. (Amended) The prostatic stent~~device~~ of claim 1 wherein the body member includes at least one protrusion to aid retention of the body member substantially within the prostatic section of the urethra.

8. (Amended) The prostatic stent~~device~~ of claim 1 wherein the body member comprises a flexible, compliant material capable of maintaining the lumen when located within the urethra.

9. (Amended) The prostatic stent~~device~~ of claim 1 further comprising a suture extending from the prostatic stent~~medical device~~ through the urethra, and terminating externally of the meatus to allow removal of the prostatic stent~~medical device~~ from the urethra by pulling the suture.

13. (Amended) The prostatic stent-catheter system according to claim 12 further comprising:

- (a) a pushing device slidably receivable by the prostatic stent-catheter system, the pushing device including an insertion end and an external end, the pushing device sized to allow the insertion end to contact the retaining member~~proximal end portion~~ of the stent while the external end remains outside the patient's body; and
- (b) a handle secured to the distal end of the connecting segment, the handle including at least one opening to allow fluid drainage out of the handle, and a mechanism, the mechanism being attached to the pushing device to allow a physician to control the position of the pushing device within the lumen of the connecting segment and the lumen of the stent.

14. (Amended) The prostatic stent-catheter system~~handle~~ according to claim 13 wherein moving the mechanism on the handle:

- (a) to a first position proximally extends the pushing device resulting in the collapse of the retaining member of said stent,
- (b) to a second position proximally retracts the pushing device resulting in the expansion of the retaining member of said stent, and
- (c) to a third position proximally retracts the pushing device resulting in the absence of contact between the pushing device and the retaining member~~proximal end portion~~ of said stent.

15. (Amended) The prostatic stent-catheter system~~pushing device~~ according to claim 13 wherein the insertion end of the pushing device is straight.

16. (Amended) The prostatic stent-catheter system~~pushing device~~ according to claim 13 wherein the insertion end of the pushing device is curved.